PLANNING GRANTS FOR MULTIPURPOSE CLINICAL RESEARCH CENTERS

Release Date: December 4, 1998

RFA: AR-99-002

P.T.

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Letter of Intent Receipt Date: March 17, 1999
Application Receipt Date: April 28, 1999

PURPOSE

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) invites applications for Planning Grants to support the development of multidisciplinary Multipurpose Clinical Research Centers (MCRCs).

The aim of the MCRC program is to support a full range of outstanding multidisciplinary clinical research on arthritis, musculoskeletal and skin diseases. Each MCRC will be organized around a biostatistics/research design core and will be expected to include a minimum of three highly meritorious projects encompassing clinical research drawing from different disciplines. The biostatistics/research design core will be the foundation of the center, providing key support for development and implementation of clinical projects. Each project must address a critical issue that directly involves assessment and/or outcomes for patients with one or more of the many chronic diseases within the mission of the NIAMS.

The one year planning grant is expected to facilitate the development of an organizational infrastructure necessary for the establishment of an MCRC and the submission of an application to support its activities.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Planning Grants for Multipurpose Clinical Research Centers, is related to the

priority area of chronic diseases. Potential applicants may obtain a copy of "Healthy People 2000" at http://www.crisny.org/health/us/health7.html.

ELIGIBILITY REQUIREMENTS

Applications may not be submitted by organizations that have held a NIAMS P60 grant (Multipurpose Arthritis and Musculoskeletal Diseases Center (MAMDC)) in the past five years. This exclusion is made because these organizations have developed the infrastructure needed for the new MCRCs through the Education, Epidemiology, and Health Services Research (EEHSR) component of the MAMDC.

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible for center grants. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators.

MECHANISM OF SUPPORT

This RFA will use the Planning Grant (P20) award mechanism. The planning, direction, and execution of the proposed project are solely the responsibility of the applicant. The total project period for an application submitted in response to this RFA may not exceed 1 year. This RFA is a one-time solicitation with an anticipated award date of September 1999.

FUNDS AVAILABLE

The NIAMS intends to commit approximately $1.0 million in FY 1999 to fund about seven grants in response to this RFA. An applicant may request a project period of one year and a budget for direct costs of up to $100,000 (exclusive of facilities and administrative costs of subcontracts with collaborating organizations). Although the financial plans of the NIAMS provide support for this program, awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of applications of outstanding scientific and technical merit.

RESEARCH OBJECTIVES

Background

NIAMS has completed a review of its Centers Program. The Institute, guided by the report from the Centers Working Group II (see http://www.nih.gov/niams/reports/cenrptfn.htm), discussions with the NAMS Advisory Council and discussions with the research community in various formats, including a series of nationwide video conferences during the summer of 1998, has determined that the Multipurpose Arthritis and Musculoskeletal Diseases Centers (MAMDCs) will be discontinued. Centers formerly funded as MAMDCs will be eligible to apply for both the new Multipurpose Clinical Research Centers (P60) and for Core Centers (P30s). The new P60 centers will be known generically as Multipurpose Clinical Research Centers (MCRCs) and each will have a maximum direct cost of $800,000 a year (exclusive of facilities and administrative costs of subcontracts with collaborating organizations). The core center program currently encompasses Skin Diseases and Musculoskeletal Disorders and will be expanded in FY 2001 to include Rheumatic Diseases. Core centers currently have a maximum direct cost of $400,000 a year (exclusive of facilities and administrative costs of subcontracts with collaborating organizations).

Goals

The goal of this RFA is to encourage research groups at institutions that have not held a MAMDC grant in the past five years to develop the organizational infrastructure needed for the new NIAMS MCRCs. It is the intent of this RFA to offer support for collaborative planning and development of the organizational infrastructure necessary for an MCRC to focus on clinical research in one or more of the NIAMS disease areas utilizing a spectrum of clinical research approaches.

Clinical Research Defined

Clinical research has been defined in the NIH Director's Panel on Clinical Research Report (Nathan Report) of December 1997. (see http://www.nih.gov/news/crp/97report/index.htm) This report states that Clinical research includes a) patient-oriented research, b) epidemiologic and behavioral studies, and c) outcomes research and health services research. Patient-oriented research is research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. This area of research includes: a) mechanisms of human disease; b) therapeutic interventions; c) clinical trials; and d) development of new technologies. Excluded from this definition are in vitro studies that utilize human tissues but do not deal directly with patients." Note: There should be no research utilizing animals or animal models included in the clinical research projects within an MCRC.

Objectives of the new Multipurpose Clinical Research Centers

The goal of the new Multipurpose Clinical Research Center (MCRC) program is to assess and improve outcomes for patients with arthritis and rheumatic diseases; musculoskeletal disorders including orthopaedics and bone diseases; muscle diseases; and skin diseases. For a comprehensive listing of the disease areas covered in the NIAMS extramural programs, please see http://www.nih.gov/niams/grants/gen2.html.

o Any given MCRC will not be expected to include all disease areas defined above or all clinical approaches included in the NIH definition of clinical research. An MCRC can focus on one or more diseases. However, two or more clinical approaches (as included in the above definition of clinical research: patient- oriented research, epidemiologic and behavioral studies, outcomes research and health services research) must be encompassed by the projects supported in the MCRC.

o Each MCRC will define its research base, goals for promoting clinical research utilizing that research base, and how multidisciplinary research will be promoted. The interaction with a General Clinical Research Center (GCRC), if present, must be documented.

o An MCRC is not a mechanism to support a large clinical trial, but proof of concept trials may be appropriate. In addition, research on animals and animal models should not be proposed in the MCRC application.

The key elements of an MCRC will include:

1) a center director and advisory committee with outstanding credentials for promoting clinical research;

2) a research base that encompasses one or more of the diseases within the NIAMS mission and provides professional and patient resources for developing clinical projects using more than one clinical research approach;

3) a biostatistics/research design core that will play a key role in the design and implementation of ALL projects supported through the center; and

4) a minimum of three highly meritorious clinical research projects that encompass one or more of the disease areas within the NIAMS mission and utilize the biostatistics/research design core.

Optional elements of an MCRC are (a) a developmental project supported by the biostatistics/research design core and lasting no more than three years and (b) other core(s) supportive of two or more of the proposed projects.

The director of the MCRC, aided by an advisory committee and the biostatistics/research design core, is expected to provide leadership to focus all research projects on clinically relevant issues to improve patient outcomes and to assure a rigorous research approach. The proposed director should document this leadership with examples of the ability to network with colleagues from clinical and other areas of biomedical research.

A biostatistics/research design core is a required component of the MCRC and must serve all projects proposed in the center. The core should have sufficient professional personnel to provide an interactive leadership role not only in supporting the projects within the MCRC, but also promoting rigorous methodologic and biostatistical support for the research base. Other cores supporting two or more of the research projects proposed may be requested.

A minimum of three highly meritorious clinical research projects, each with a focus to assess and/or improve outcomes for patients, must be present in an MCRC. Each project will define the patient problem under study and the anticipated improvement in assessment and/or outcome for the patient that might be realized through this project. The projects must represent two or more general areas of clinical research (see the NIH definition of clinical research included in this document).

An optional component in an MCRC is a development and feasibility project lasting no more than three years. The goal of the development and feasibility project should be to gather preliminary data or to develop a resource for a future study.

Objectives of the Planning Grant

NIAMS seeks to expand on the success of the education, epidemiology, and health services research (EEHSR) component of the MAMDC program through the new MCRC program. Through this RFA, NIAMS encourages new collaborative efforts to address critical issues directly affecting assessment and outcomes for patients with diseases within the mission of NIAMS. Where appropriate, more than one institution may collaborate in an MCRC. The collaborations must draw from a spectrum of clinical research approaches (see the definition of clinical research). Illustrative, but not all-inclusive, examples include proof of concept research, clinical epidemiology, health services research, rehabilitation research, social sciences research, and

educational/behavioral research. The new organizational infrastructures are expected to provide the basis for establishment of new MCRCs.

The application for a planning grant should document the potential and plans for identifying and developing the following:

1) the resources for a biostatistics/research design core that can guide the planning and implementation of clinical projects;

2) a research base for development of clinical research projects in one or more of the NIAMS disease areas drawing from two or more clinical research approaches (see the definition of clinical research); and

3) a director and advisory group who can promote the translation of critical patient needs to various research disciplines for clinically meaningful assessments and/or outcomes.

Scientific resources covering a wide spectrum of coordinated research efforts in addition to key personnel and resources should be identified. Organizational plans and agreements should be established. In these planning efforts, applicants are strongly encouraged to identify and, where possible, secure commitments for complementary resources that would expand the potential scientific yield of MCRC activities.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and in the NIH Guide for Grants and Contracts, Vol. 23, No. 11, March 18, 1994, available on the web at: http://grants.nih.gov/grants/guide/notice-files/not94-105.html.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: http://grants.nih.gov/grants/guide/notice-files/not98-024.html.

LETTER OF INTENT

Prospective applicants are asked to submit, by March 17, 1999, a letter of intent that includes a descriptive title of the proposed research, the name, address, telephone number, FAX, and email address of the Principal Investigator, the identities of other key personnel and potential participating institutions and departments and the number and title of this RFA. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains is helpful in planning for a timely review of the applications. It allows NIAMS staff to estimate the potential review workload and to avoid possible conflicts of interest in the review.

The letter of intent is to be sent to Dr. Julia Freeman at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Prospective applicants are encouraged to communicate with program and grants management staff of the NIAMS's Extramural Program as early as possible in the planning phase of application preparation.

The research grant application form PHS 398 (rev. 4/98) is to be used in applying for these grants. Application kits are available at most institutional offices of sponsored research and from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone (301) 435-0714, email: GrantsInfo@nih.gov. Applications are also available on the World Wide Web at

http://grants.nih.gov/grants/forms.htm.

The page limitation for the research plan will be 15 pages for this planning grant, rather than the 25 page limitation noted in the form PHS 398 instructions.

The following are suggestions for organizing the planning grant application to maintain the form PHS 398 format and facilitate review of the applications. However, see the review criteria at the end to insure that the application contains material to allow full evaluation.

1. Face page with (1) the title reading "Planning Grant for a Multipurpose Clinical Research Center" and (2) RFA information reading "AR-99-002" and "Planning Grant." Dates of support will be 9-1-99 to 8-31-00.

2. Abstract page with a list of (a) key personnel for the planning grant and (b) key personnel for the research base.

3. Table of Contents. Adapt the Table of Contents for this application.

4. One year budget with justification. Costs requested may include partial support for the principal investigator and other key professionals, administrative support, consultants, travel and supplies. Equipment items, patient costs and maintenance contract costs are not appropriate.

5. Budget for the Entire Proposed Period of Support. This will reflect only one year.

6. Biographical sketch. Include sketches for key personnel in the research base as well as for the key personnel on this grant application.

7. Other support. Include other support pages for key personnel in the research base as well as for the key personnel on this grant application.

8. Resources and Environment. List the schools, laboratories, clinics, centers, existing cores and other resources that will be part of the research base.

9. Research plan. Limited to 15 pages. Adapt the sections of form PHS 398 for this program:
a. Specific Aims - List the elements of the proposed planning process.
b. Background and Significance - Describe the goal of the planning process.

This can include the research environment and key research areas for development into clinical research. Indicate how combining these areas is expected to result in synergy.
c. Preliminary Studies - Describe the programs in place that will be the research base for core and program development.
d. Research Design - Include the following elements: (1) the plan and time line for developing the organizational infrastructure to identify, evaluate and select projects and cores, (2) the resources available for a biostatistics/research design core, (3) the qualifications of the proposed director and how the director will integrate the components of the research base, and (4) the use of advisory group(s).

10. Letters of support from key individuals endorsing the development of an MCRC should be included as one section within the application. These key individuals should include expected major collaborators from the research base and administrative officials (such as chairmen, deans, etc) who will provide the institutional oversight/support. Appendix may not be used to circumvent page limitations.

The RFA label available in the PHS 398 application form kit must be affixed to the bottom of the face page of the original and the original must be placed on top of the entire package. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review.

Submit a signed, original of the application, including a cover letter, the checklist, and three signed photocopies, in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application must also be sent to:

Dr. Tommy Broadwater
Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS-25U, MSC 6500
Bethesda, MD 20892-6500

Applications must be received by April 28, 1999. If an application is received after that date, it will be returned to the applicant without review.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the Center for Scientific Review (CSR) and responsiveness by the NIAMS. Incomplete applications or those that exceed the budget limit of $100,000 direct costs will be returned to the applicant without further consideration. If NIAMS staff find that the application is not responsive to the RFA, it will be returned without further consideration.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIAMS in accordance with the standard NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, assigned a priority score, and receive a second level review by the National Advisory Arthritis and Musculoskeletal and Skin Diseases Council.

Factors to be considered in the evaluation of the P20 planning grant applications are:

(1) Significance: What is the merit of the research base described and the plans for developing important clinical research projects from that research base? How compelling is the rationale for the research base designated and the clinical approaches identified? What is the merit of plans for developing a biostatistics/research design core? Does the planning process seem likely to lead to a unique or significant MCRC?

(2) Approach: What is the adequacy of the administrative structure for planning a future MCRC, including the following elements: the relationship to and support by the parent institution, the planning process and time line that will be used, the areas for project development, the advisory and evaluation mechanisms for selecting projects, and the plans for developing core facilities, especially a biostatistics/research design core?

(3) Innovation: Will existing institutional resources contribute to the success of a future MCRC? Will the proposed planning process promote multidisciplinary and collaborative research beyond that currently present?

(4) Investigator: Do the qualifications of the key personnel document expertise to lead the translation of important clinical issues into meaningful research projects? Does the director have the scientific and administrative qualifications, experience and commitment to provide effective leadership among various disciplines needed for the MCRC?

(5) Environment: What is the quality of the research base for developing significant clinical research projects for the MCRC? Are there adequate resources to develop a biostatistics/research design core? Is there evidence of the availability of appropriate study populations and ability to recruit patients consistent with the NIH guidelines for gender, minority and children inclusion? Is there evidence of support by key collaborators?

AWARD CRITERIA

Applications recommended for further consideration by the National Advisory Arthritis and Musculoskeletal and Skin Diseases Council will be considered for funding on the basis of overall scientific, clinical, and technical merit of the proposal as determined by peer review, how well the application meets the goals and objectives of the program as described in this RFA, including increasing the concentration of funded activities in clinical research, appropriateness of budget estimates, program needs and balance, policy considerations, adequacy of provisions for the protection of human subjects, and availability of funds.

The earliest anticipated date of award is September 1999.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Dr. Julia B. Freeman
Centers Program
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS-19F, MSC 6500
Bethesda, MD 20892-6500
Telephone: (301) 594-5052
FAX: (301) 480-4543

Email: freemanb@exchange.nih.gov

Direct inquiries regarding grants management issues to:

Ms. Sally A. Nichols
Grants Management Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS-49F, MSC 6500
Bethesda, MD 20892-6500
Telephone: (301) 594-3535
FAX: (301) 480-5450
Email: nicholss@exchange.nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.846. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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